

## **REMARKS**

### **Introduction**

Claims 8, 16, and 17 are pending. The remaining claims are withdrawn. Claims 8 and 17 have been amended. Support for these amendments can be found throughout the specification, for example, in the claims as filed and Figure 7. No new matter has been introduced.

### **Rejection under 35 U.S.C. §101**

The Examiner has rejected claims 8, 16, and 17 under 35 U.S.C. §101 because the claimed invention is allegedly not supported by either a specific and substantial credible asserted utility or a well-established utility. Applicants disagree for at least the following reasons.

The specification discloses that foap-13 is associated with neurodegenerative disease, including Alzheimer's disease (AD). Specifically, the specification shows that foap-13 is differentially expressed in samples from patients with AD when compared to samples from healthy control persons. For example, Figure 3 shows the differential expression of the foap-13 gene in AD patient versus healthy controls. This test, performed using RT-PCR, indicates that persons with AD exhibit differential expression of foap-13 in the temporal cortex relative to the frontal cortex. *See* paragraph [0059] of the specification; *see also* Figure 2 (showing differential expression of foap-13). The specification then lists at paragraph [0018] that this differential expression has "utility for the diagnostic evaluation and prognosis as well as for the identification of a predisposition to a neurodegenerative disease, in particular AD." Thus, foap-13 expression is a marker for at least AD.

The pending claims, as amended, are directed to assays for testing compounds to determine the degree of binding of the compounds to the protein in SEQ ID NO. 2 (foap-13). These assays have at least the specific and credible use of being used to detect the disclosed marker (foap-13 expression) to determine whether a patient has AD or other neurodegenerative diseases, as the specification has described and shown with examples. This is a specific use that is credible and of great value to patients seeking identification and diagnosis of AD, physicians seeking to treat

patients with AD or at risk for AD, and to the health care system in general. Therefore, the rejection under 35 U.S.C. §101 is improper and Applicant respectfully requests that it be withdrawn.

Rejections under 35 U.S.C. §112

The Examiner has rejected claims 8, 16, and 17 under 35 U.S.C. §112 first paragraph as allegedly lacking a specific or credible utility and therefore, allegedly, one of skill in the art would not know how to use the claimed invention. Applicant has provided such a utility above and those arguments apply equally to this rejection.

Further, the specification provides ample support for how to perform the assay of claim 8 to determine the degree of binding of the test compound to the protein in SEQ ID NO. 2. One of skill in the art would appreciate how to use such an assay to determine the degree of binding as well as how to perform a compound to protein binding assay using the methods known in the art and provided in the specification.

The Examiner has also rejected of claims 8, 16, and 17 under 35 U.S.C. §112 first paragraph based on the inclusion of the phrase pertaining to fragments, derivatives, and variants of the foap-13 protein. Solely to expedite prosecution, Applicant has amended the claims to remove this phrase.

The Examiner has also rejected claims 8, 16, and 17 as allegedly being vague because of the term "foap-13 protein." Applicant disagrees, however, solely to expedite prosecution, the claims have been amended. The term foap-13 protein has been replaced with SEQ ID NO. 2, which contains the sequence of the foap-13 protein. Therefore, the metes and bounds of the amended claims can readily be determined.

Claim 17 has also been amended to change the term "fluorescence" to fluorescent in response to the Examiner's rejection. This rejection is now moot.

Application No. 10/525,726  
Amendment dated October 16, 2007  
Reply to Office Action of July 16, 2007

Docket No.: 37998-237386

For at least the above reasons, the rejections under 35 U.S.C. §112 are either improper or moot. Applicant respectfully requests that all the rejections under 35 U.S.C. §112 be withdrawn.

In view of the above amendment, Applicant believes the pending application is in condition for allowance.

Dated: October 16, 2007

Respectfully submitted,

By 

Matthew E. Kelley

Registration No.: 55,887

VENABLE LLP

P.O. Box 34385

Washington, DC 20043-9998

(202) 344-4000

(202) 344-8300 (Fax)

Attorney/Agent For Applicant